

USAMRMC CONTROL NUMBER:

DEPARTMENT OF THE ARMY CONTROL NUMBER:

**NON-EXCLUSIVE
LICENSE AGREEMENT**

THIS LICENSE AGREEMENT (“*Agreement*”), effective as of the “Signature Date” (as defined below), is made by and between: [Laboratory] (; Licensor), a subordinate laboratory of the U.S. Army Medical Research and Materiel Command (USAMRMC) having an address at 504 Scott Street, Fort Detrick, Maryland 21702-5012, U.S.A.; and [] (“*Licensee*”), a [] corporation, having its principal place of business at [].

ARTICLE I

BACKGROUND

1.1 The United States of America is the owner by assignment or otherwise of the entire right, title and interest to inventions more particularly described and claimed in each of the patents and patent applications, including provisional applications, as well as all rights corresponding thereto, listed on **Schedule 2.16 – A (Existing Patents)** (collectively, the “Existing Patents”).

1.2 Under the authority of 15 United States Code 3701 et seq., 35 United States Code Sections 200 - 210, and 37 Code of Federal Regulations, Chapter IV (together with any amendments and the underlying rules and regulations now or hereafter promulgated collectively, the “*Federal Technology Transfer Act*” or the “*FTTA*”), Licensor has custody of inventions described and claimed in, and the right to issue licenses under, the Existing Patents.

1.3 Licensor desires that the inventions described and claimed in the Existing Patents be brought to the “Point of Practical Application” (as defined below) in the shortest possible time and made available to the public, thereby serving the public interest and broadening the potential supply base for Licensor and U. S. government agencies.

1.4 Licensee desires to obtain a nonexclusive license under the Existing Patents for the purpose of developing and commercializing products to be used []. Licensee understands and acknowledges that any and all inventions and technology related to or arising out of the Existing Patents would now and hereafter be subject to and governed by the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the premises noted above, including the above-cited statutory authority, and the mutual promises, covenants, duties and obligations hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Licensor and Licensee, intending to be lawfully bound, do agree as follows:

ARTICLE II

DEFINITIONS

The terms defined in this Article II shall have the meanings set forth below throughout this Agreement.

2.1 **“Additional Information”** shall have the meaning set forth in Article V hereof.

2.2 **“Affiliate(s)”** means any corporation or other legal entity that controls, is controlled by, or is under common control with Licensee. For purposes of this definition, "control" (including, with correlative meanings, the terms “controlled by” and “under common control with”), means, whether de jure or de facto, the ownership, directly or indirectly, of more than fifty percent (50%) of the outstanding equity securities of a corporation which are entitled to vote in the election of its Board of Directors or more than fifty percent (50%) interest in the net assets or profits of an entity which is not a corporation. Licensee shall initially and continuously identify, designate and update its relationship with each Affiliate on Schedule 2.2 (Affiliates) attached hereto and made a material part hereof, amended or supplemented from time to time after notice and with approval of Licensor as contemplated and permitted under Section 3.1 herein below.

2.3 **“Agreement”** means this agreement.

2.4 **“Bankrupt”** means when any Person shall (a) apply for or consent to the appointment of, or the taking of possession by, a receiver, custodian, trustee or liquidator of any of the assets of same; (b) admit in writing an inability, or be generally unable, to pay debts as they become due; (c) make a general assignment for the benefit of creditors; (d) commence a voluntary case under the federal bankruptcy laws (now or hereafter in effect); (e) be adjudicated a bankrupt or insolvent; (f) file a petition seeking to take advantage of any other law providing for the relief of debtors; (g) acquiesce to, or fail to have dismissed, within thirty (30) days, any petition filed in any involuntary case under such bankruptcy laws; or (h) take any action for the purpose of effecting any of the foregoing.

2.5 **“Board”** means the Board of Directors of Licensee or an Affiliate, as it may apply.

2.6 **“Confidential Information”** shall mean (a) any proprietary or confidential information or material in tangible form disclosed in accordance with this Agreement that is marked as “Confidential,” “Proprietary” or the like at the time it is delivered to the receiving party, (b) proprietary or confidential information disclosed orally hereunder which is identified as confidential or proprietary when disclosed and such disclosure of confidential information is confirmed in writing within thirty (30) days by the disclosing party, or (c) Trade Secrets of Licensor regardless of whether or not so marked or identified. For purposes of this Agreement, “Confidential Information” shall not include information that can be established by the receiving party by competent proof that such information:

- (i) was already known to the receiving party, other than under an obligation of confidentiality, at the time of disclosure;

- (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party;
- (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving party in breach of this Agreement;
- (iv) was subsequently lawfully disclosed to the receiving party by a person other than a party hereto; or
- (v) was lawfully developed independently by the receiving party without misappropriating confidential information from a third party.

2.7 **“Development Plan”** means the comprehensive plan and related exhibits, schedules and agreements prepared and undertaken by Licensee to commercialize the Licensed Patent Technology for the sole benefit of Licensor substantially in the form of Schedule 2.7 (Development Plan) attached hereto and made a material part hereof, amended or supplemented from time to time after notice and with approval of Licensor.

2.8 **“End User”** means any Person with the right to use Licensed Products for his/her own personal use or in the regular conduct of its own business and not for licensing to other Persons.

2.9 **“Event of Default”** shall have the meaning used in Article XI.

2.10 **“Existing Patents”** shall have the meaning used in Article I.

2.11 **“FTTA”** shall have the meaning used in Article I.

2.12 **“Government”** means the federal government of the United States of America.

2.13 **“Improvement”** means any revision, translation, abridgement, condensation, expansion, modification or any other form in which an invention may be recast, transformed or adapted, provided any such modification or adaptation would, if unlicensed, infringe on the Licensed Patent Technology. For purposes hereof, an Improvement shall also include any enhancement or derivative work, product, device or invention that incorporates a preexisting work, product, device or invention.

2.14 **“Intellectual Property Rights”** means, solely with respect to the Licensor, any or all of the following, in any and all jurisdictions throughout the world, and all rights in, arising out of, or associated with: (a) all patents (including Existing Patents and the Licensed Patent Technology) and applications therefore, including provisional applications, and all reissues, divisions, renewals, extensions, reexaminations, continuations and continuations-in-part thereof ("Patents"); (b) all rights (other than Patents) in inventions (whether patentable or not), invention disclosures, formulations, pre-clinical data, clinical data, laboratory data, manufacturing processes, processes, methods, techniques, trade secrets, proprietary information, know-how, technology and technical data ("Trade Secrets"); (c) all copyrights, copyright registrations and

applications therefore and all other rights corresponding thereto ("Copyrights"); (d) all mask works, mask work registrations and applications therefore; (e) all industrial designs and any registrations and applications therefore; (f) any other rights in databases and data collections; (g) any other rights in computer software including all source code, object code, firmware, development tools, files, records and data, and all media on which any of the foregoing is recorded; (h) all know-how and show-how, techniques, design rules, ideas, concepts, methods, algorithms, formulae, discoveries, compositions, routines, files, works of authorship, processes, prototypes, devices and hardware whether or not protectible by Patents, Copyrights or Trade Secrets; and (i) any similar, corresponding or equivalent rights or Improvement in which Licensor has property rights to any and all of the foregoing and any other intellectual property or proprietary rights, whether or not registrable; including, without limitation, any and all trademarks, trade names, domain names, logos and service marks and any similar indications of origin or branding expressly reserved for use by or identified with Licensor, unless otherwise stated.

2.15 ***"Licensed Field of Use"*** means [_____] applications or uses for the Licensed Patent Technology.

2.16 ***"Licensed Patent Technology"*** means all of Licensor's rights in but limited to (a) the Existing Patents listed on ***Schedule 2.16 – A (Existing Patents)***, attached hereto and made a material part hereof, including any extensions, reissues and reexaminations thereof, and (b) any and all additional patents, patent applications or ancillary Intellectual Property Rights explicitly added with the approval of Licensor on ***Schedule 2.16 - B (Additional Patents and Patent Applications)***, attached hereto and made a material part hereof, including any extensions, reissues and reexaminations thereof, subject to the terms and conditions of this Agreement. Licensed Patent Technology shall include any and all divisions, continuations, and substitutions related to the patents and patent applications referenced in subsections (a) and (b) of this Section; all foreign patent applications corresponding to the foregoing applications; and all U.S. and foreign patents issuing on any of the foregoing applications, including extensions, reissues, and reexaminations. ***Schedule 2.16 – A and B*** may be amended or supplemented from time to time in the sole discretion of Licensor.

2.17 ***"Licensed Product(s)"*** means any and all products, methods, inventions or devices of any kind and the information related thereto which either (a) fall within or are covered by the scope of one or more Valid Claims of the Licensed Patent Technology; (b) are made for use in the practice of a method or process that is within the scope of one or more Valid Claims of the Licensed Patent Technology; or (c) are produced by, related to, derived or compiled from or employ products, methods, inventions, devices, substances, techniques, processes, systems, formulations, or designs described in the Licensed Patent Technology, in the country of use, manufacture or sale by Licensee or its Affiliate(s).

2.18 ***"Licensed Territory"*** means [_____].

2.19 ***"Licensee"*** means [_____].

2.20 ***"License Fee(s)"*** has the meaning set forth in Article IV.

2.21 **“Licensor”** means [_____], as a representative of the United States of America.

2.22 **“Licensor’s Director”** means the Director of Licensor, or if such post is vacant or has been eliminated, then the representative within or overseeing Licensor who is authorized to approve, and execute on behalf of Licensor, this Agreement.

2.23 **“Licensor’s Representative”** means U.S. Army Medical Research and Materiel Command, Staff Judge Advocate (MCMR-JA), 504 Scott Street, Fort Detrick, Maryland 21702-5012, Attn: USAMRMC ORTA.

2.24 **“Net Sales”** means the actual gross amount billed, invoiced, charged or received on sales or transfers of any Licensed Products by Licensee or its Affiliate(s) to any and all Unaffiliated Person(s), or in the event of disposal of any Licensed Products other than as scrap prior to shipment from its place of manufacture or predisposal storage, or other than by sales, the amount billed, invoiced, charged or received on sales or transfers for a like quantity and quality of Licensed Products to Unaffiliated Persons on or about the time of such disposal, less:

(a) trade, cash and quantity discounts, including charge backs, rebates, premiums, allowances and any other deduction actually granted to the Unaffiliated Person (not to exceed the original billing);

(b) sales and excise taxes and duties and any other governmental charges imposed upon the importation, use or sale of the Licensed Products actually charged to the Unaffiliated Person;

(c) freight, insurance and other transportation charges actually charged to the Unaffiliated Person; and

(d) amounts repaid or credited (not to exceed the original billing) by reason of rejections, defects, outdating, price differences, recalls or returns, or because of retroactive price reductions, or due to governmental laws or regulations requiring rebates actually granted to the Unaffiliated Person.

The cumulative total of deductions specified above shall not decrease Net Sales by more than one-third compared to Net Sales calculated without consideration of these deductions.

For purposes of calculating Net Sales for any reporting period, any and all deductions used in calculating Net Sales are allowable only to the extent that they have already been included in the amounts billed, invoiced, charged or received or granted on the sales or transfers of Licensed Products by Licensee or its Affiliates to Unaffiliated Persons in bona fide arms’ length transactions. Calculation of Net Sales shall be in accordance with generally accepted accounting principles. Sales or transfers of Licensed Products between or among Licensee and its Affiliate(s) shall be excluded from the computation of Net Sales except where such Affiliate(s)

are End Users, but Net Sales shall include the subsequent final sales or transfers to Unaffiliated Persons by such Affiliate(s) (if not End Users).

In the case of a Licensed Product utilizing a combination of properties other than Licensed Product properties, solely for purposes of determining what percentage of License Fees are owed to Licensor hereunder, Net Sales shall be multiplied by $A/A+B$, where A is the invoice price of the Licensed Products sold separately and B is the invoice price of the active properties in the combination of properties other than Licensed Product properties. If the invoice price of the Licensed Products and/or of the active properties in the combination is (are) not available and the parties are unable to agree on an alternative arrangement, then in lieu and stead of the fraction noted above Net Sales shall be multiplied by X/Y , where X is one (1) and Y is the total number of active properties included in the combination.

2.25 **“Patent Prosecution Fees”** shall have the meaning set forth in Article IV.

2.26 **“Person”** means any natural person or entity including, without limitation, any individual, partnership (whether general or limited), limited liability company, corporation, trust, estate, association, nominee, firm, unincorporated organization or a government or agency or political subdivision thereof.

2.27 **“Point of Practical Application”** means to manufacture, practice, or to operate inventions, described and claimed in the Licensed Patent Technology, under such conditions as to establish that the inventions are being utilized and that their benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms within [] year(s) of the Signature Date, and to continue during the term of this Agreement to make the benefits of the inventions reasonably accessible to the public, consistent with sound and reasonable business practices and judgment. If Licensee believes that it will be unable to make such products available to the public within such time frame, it shall give notice to Licensor by way of a detailed explanation specifying the reasons therefore. Licensee may amend the time period at any time with the written consent of Licensor. Unless Licensee has failed to perform its duties and obligations under this Agreement, Licensor shall not unreasonably withhold approval of any request by Licensee to extend the time period if such request is supported by a reasonable showing that Licensee has in accord with the Development Plan taken diligent steps consistent with sound and reasonable business practices and judgment to commercialize the Licensed Patent Technology, taking into account any change in circumstances, scientific developments, or other factors considered by the parties relevant for adopting a new time frame.

2.28 **“Point of Practical Application Reports”** shall have the meaning set forth in Article V.

2.29 **“Regulatory Authority”** means any foreign union, country, state, or nation and its governmental department, body, commission, board, bureau, agency or instrumentality with applicable regulatory jurisdiction.

2.30 **“Reports”** shall have the meaning set forth in Article V.

2.31 **“Signature Date”** means the date that this Agreement is last executed by Licensor’s Director.

2.32 **“Unaffiliated Person(s)”** means any Person and shall include, without limitation, an End-User and the joint venture partner, company or other entity that also has non-controlling outstanding equity securities of Licensee or an Affiliate or has a non-controlling interest in the net assets or profits of Licensee or an Affiliate.

2.33 **“USFDA”** means the U.S. Food and Drug Administration.

2.34 **“USPTO”** means the U.S. Patent and Trademark Office.

2.35 **“Valid Claim”** means a claim of an issued and unexpired patent included within the Licensed Patent Technology which either has not been (a) held unenforceable or invalid by a court or other governmental agency of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, or (b) admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

ARTICLE III

LICENSE GRANT

3.1 In consideration of the payment of all License Fees and subject to full compliance with the terms and conditions of this Agreement by Licensee, Licensor grants to Licensee a nonexclusive license under the Licensed Patent Technology, without the right to grant and authorize sublicenses, to make, import, use, offer for sale, and sell Licensed Products throughout the Licensed Territory in the Licensed Field of Use for the term of this Agreement and for the purpose stated in Article I. Licensee shall have the right to extend this license to any Affiliate of its choice, provided that each such extension properly references and is made subordinate to this Agreement, including those rights retained by Licensor hereunder, subject to and consistent with the approval requirements of the United States Code, Title 35, Part II, Chapter 18, Section 209 (as amended) and U.S. Presidential Executive Order No. 12591.

3.2 No right or license is granted or implied to Licensee or to any Affiliate or Person claiming through or under Licensee respecting any licensed patent or licensed patent application other than that specifically identified herein as the Licensed Patent Technology and the corresponding Licensed Field of Use. Nothing herein shall be construed as granting Licensee, by implication, estoppel or otherwise, any license or other right under or respecting any unlicensed Intellectual Property Rights of Licensor, except for those rights expressly granted under the Licensed Patent Technology and the corresponding Licensed Field of Use. Licensor specifically retains all residual rights and interests in and to the Licensed Patent Technology and its unlicensed Intellectual Property Rights and neither Licensee or its Affiliate(s) shall act in a manner that would or could impair or conflict either with the residual rights and interests of Licensor or the grant afforded to Licensee hereunder.

3.3 In full compliance and accordance with the FTTA, Licensee grants to Licensor a royalty-

free, nonexclusive, worldwide license to practice and have practiced on behalf of the Government, and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the Government, any Improvement made by Licensee or its Affiliates for the term set forth in Article XI of this Agreement.

ARTICLE IV

LICENSE FEES: ROYALTIES AND PAYMENT OF OTHER INCOME

4.1 Licensee shall make payment and insure payment in full is made of all royalties and fees due and owing to Licensors under this Article IV (collectively hereinafter the “*License Fee(s)*”) described as follows:

(a) Within 45 days after the Signature Date, Licensee shall pay to Licensors an execution fee of [_____ and _____ thousand dollars (\$____,000)], no part of which shall be refunded for any reason.

(b) From and after the Signature Date throughout the term, Licensee shall continuously pay to Licensors an annual minimum royalty of [_____ Thousand Dollars (\$____,000)]. The first annual minimum royalty shall be prorated for the balance of the calendar year remaining after the Signature Date, payable within 45 days after December 31 of the year in which this Agreement is executed as evidenced by the Signature Date. Subsequent annual minimum royalties shall accrue on December 31 of each year and shall be payable within 45 days thereafter during the term of this Agreement. No part of any annual minimum royalty payment shall be waived or refunded for any reason. The annual minimum royalty paid when due by Licensee for any given year shall be applied as a credit solely against any royalty on Net Sales generated and accrued for that year.

(c) From and after the Signature Date but before sales to Unaffiliated Persons occur, Licensee shall make certain milestone payments to Licensors corresponding to the product development cycle for each and every prototype Licensed Product under development for use in the United States or in any sovereign state with a Regulatory Authority. Licensee shall make such milestone payment to Licensors according to the following schedule:

(i) Licensee shall pay to Licensors the sum of [____ thousand dollars (\$____,000)] due within 45 days of [the successful conclusion of the first Phase I testing by Licensee or its Affiliates of each such Licensed Product]. For purposes of this subsection, [successful conclusion of Phase I testing] shall mean that the USFDA or the Regulatory Authority has approved the transition from [Phase I to Phase II testing].

(ii) Licensee shall pay to Licensors the sum of [____ thousand dollars (\$____,000)] due within 45 days of [the successful conclusion of the first Phase II testing by Licensee or its Affiliates of each such Licensed Product]. For purposes of this subsection, [successful conclusion of Phase II testing] shall mean that the USFDA or the Regulatory Authority has approved the transition from [Phase II to Phase III testing].

(iii) Licensee shall owe to Licensors the sum of [___ thousand dollars (\$___,000)] upon [successful conclusion of the first Phase III testing by Licensee or its Affiliates of each such Licensed Product]. For purposes of this subsection, [successful conclusion of Phase III testing] shall mean that an application for regulatory approval for each such Licensed Product (e.g., NDA or BLA) has been filed with the USFDA or the Regulatory Authority.

(d) Each and every time Licensee or its Affiliate(s) obtains approval from the USFDA or a Regulatory Authority for a Licensed Product:

(i) Licensee shall pay Licensors [___ thousand dollars (\$___,000)] within 45 days after each grant of a Product License, Biological License or the equivalent by the USFDA.

(ii) Licensee shall pay Licensors [___ thousand dollars (\$___,000)] within 45 days after each grant of a Product License, Biological License or the equivalent by a Regulatory Authority.

(e) Licensee shall pay Licensors a royalty on the Net Sales of all Licensed Products sold or transferred to Unaffiliated Persons or otherwise disposed of within the Licensed Territory by Licensee or its Affiliate(s). The royalty rate for all Licensed Products shall be [____ percent (____%)] of Net Sales.

(f) Licensee agrees to reimburse and pay to Licensors [_____] Dollars (\$___,00) for Licensors' past, current and on-going patent preparation, filing, prosecution and maintenance fees and costs (collectively, the "*Patent Prosecution Fees*") incurred to date, payable in one lump sum within 45 days after the Signature Date. No part of such payment shall be refunded or waived for any reason.

(g) With respect to Licensors' subsequent patent preparation, filing, prosecution and maintenance responsibilities, fees and costs incurred throughout the term of this Agreement, Licensee shall also pay to Licensors certain amounts at the times and in the manner noted as follows:_____.

4.2 No Licensee Fee shall be payable to Licensors under this Article IV solely with respect to Licensed Products distributed without consideration on a limited, restricted basis for use in research and development or as promotional samples. Licensee shall maintain and cause to be maintained records of all such activity made available to Licensors upon request.

4.3 License Fees shall be payable until the expiration of the last-to-expire patent application or Valid Claim of the Licensed Patent Technology, including any extensions granted under the Patent Term Restoration Act or any other statute (as amended).

4.4 Payments under this Article IV shall be made in United States dollars and paid by check to "DFAS ROCK ISLAND." On a statement accompanying the check, it shall be noted that the payment is for royalties or licensing fees, and each of the patent/patent applications and United

States Department of Army log number(s) shall be listed and specifically referenced. In the case where payments of License Fees are made on more than one licensed patents/patent applications, Licensee shall submit an estimated allocation of payments amongst the relevant licensed patents/patent applications. All checks for payments under this Article IV should be mailed to DFAS -- ROCK ISLAND OPLOC, ATTN: DFAS-RI-FD, Building 68, Rock Island, IL 61299-8300, with a copy to the Licensor's Representative at the address noted herein above. All checks and bank drafts shall be good funds drawn on United States banks.

4.5 For purposes of converting currencies other than U.S. Dollars to U.S. Dollars, Licensee shall use the average of the current exchange rate as reported in *The Wall Street Journal* under the column headed "Currency Trading" and subtitled "Exchange Rates" for the last business day of each month in which License Fees were earned for the applicable reporting period; provided, however, that if such rate is not so published, then such conversion rate shall be the average of the selling rate for such currency, as published by a leading New York City bank chosen by Licensee and reasonably acceptable to Licensor, on the last business of each month in which License Fees were earned for the applicable reporting period. Any and all loss of exchange, value, taxes or other expenses incurred in the transfer or conversion of other currency to U.S. Dollars shall be paid entirely by Licensee.

4.6 Except as otherwise provided for hereunder, Licensee shall pay License Fees accrued according to Article IV and any other outstanding payments then due and payable hereunder, not later than 45 days after each calendar half year ending June 30th and December 31st. Licensee shall submit with its payment the written report required in Article V. If no License Fees are due, the report shall so state. Sales shall be deemed made, for purposes of this Section, when billed out, except that upon any termination of this Agreement, all shipments made on or prior thereto shall be considered as sold (and therefore subject to License Fee(s) or payments hereunder).

4.7 Licensee shall pay within 45 days from any termination of this Agreement all License Fees and any other amounts due Licensor hereunder accrued or accruable for payment at the time of any such termination.

4.8 License Fees and any other payments due hereunder not received by Licensor by the due dates shall be subject to interest charges computed at twelve percent (12%) per annum.

ARTICLE V

REPORTS AND RECORDS

5.1 Licensee agrees to keep records showing the gross sales, Net Sales or other disposition of Licensed Products sold or otherwise disposed of under the license appropriate to determine the amount of License Fees and other payments due Licensor hereunder. Such records, including, without limitation, those of its Affiliates, shall be retained for a period of five (5) years following the end of the calendar year to which such records pertain, and shall be treated and maintained as Confidential Information of Licensee. Such records should be in sufficient detail and clearly organized to enable the License Fees and any other amounts payable hereunder by Licensee to be determined, and Licensee further agrees to afford Licensor or its designee(s) or agent(s) access,

subject to the conditions set forth below in this Article V, to examine any and all relevant books and records of Licensee and, where appropriate, its Affiliate(s), as may be necessary to make such determination. Upon thirty (30) days prior written notice, Licensee shall make such records available for examination during normal business hours for the sole purpose of verifying the accuracy of Licensee's payments and compliance with this Agreement for any period within the most recently completed five (5) calendar years during the term of this Agreement and for five (5) years after the expiration or termination of this Agreement. If an auditor or certified public accountant is appointed by Licensor to conduct such an examination, Licensor shall, at Licensee's sole cost and expense, review and approve any reasonable request that its designee or agent execute an agreement not to otherwise disclose confidential or proprietary information. Licensee shall also assume and pay any and all audit expenses and costs incurred in the event any underpayment is reported which equals or exceeds 5% of the License Fees or other payments due Licensor hereunder. The parties agree to adhere to the rules and procedures established under the Administrative Dispute Resolution Act (5 USC Section 571, as amended) to resolve any dispute arising under this Section.

5.2 During the term of this Agreement, Licensee shall provide written annual progress reports (the "***Point of Practical Application Reports***") not later than 45 days after the calendar year ending December 31st, detailing its efforts, and the efforts of all Affiliate(s), to bring the inventions licensed under this Agreement to the Point of Practical Application, together with any additional information requested by Licensor or as contemplated and required under the Development Plan (the "***Additional Information***"). The Point of Practical Application Reports and any Additional Information shall contain reasonably sufficient information to substantiate that Licensee is in full compliance with the terms of this Agreement and that the Development Plan is being executed. No such annual progress Point of Practical Application Reports shall be required with respect to any particular Licensed Product after notification of the first commercial sale of such Licensed Product in a particular country within the Licensed Territory, unless otherwise requested by Licensor.

5.3 Concurrently with each payment of amounts due and owing Licensor under this Agreement, Licensee shall also submit a true, accurate and complete written report setting forth for the preceding six (6) month reporting period (i) the quantity of: (1) Licensed Products made, used, sold or otherwise disposed of by Licensee and its Affiliate(s), (ii) the gross and Net Sales calculations thereof, and (iii) calculation of the amounts due to Licensor under this Agreement for each such period. If no License Fees or other payments are due Licensor for any reporting period, the report shall so state (collectively, the "***Reports***").

ARTICLE VI

NO SUBLICENSING RIGHTS

Neither Licensee nor its Affiliate(s) shall grant any sublicense or exercise any rights, which are inconsistent with the rights and obligations of Licensee, or act in conflict with the residual rights of Licensor, hereunder.

ARTICLE VII

LICENSEE PERFORMANCE

7.1 Throughout the term, Licensee shall perform and shall cause its Affiliate(s) at all times to perform all of their respective duties and obligations as required hereunder and under the Development Plan and Licensee shall expend and shall cause its Affiliate(s) where and to the extent appropriate to expend reasonable efforts and resources to carry out the development and marketing of the inventions, described and claimed in the Licensed Patent Technology throughout the Licensed Territory.

7.2 After bringing the inventions, described and claimed in the Licensed Patent Technology, to the Point of Practical Application in the Licensed Territory, Licensee agrees and shall cause its Affiliate(s) to agree to keep Licensed Products available to the public during the term of this Agreement. Licensee shall promptly report discontinuance of the making of the benefits of the inventions reasonably accessible to the public.

7.3 A failure by Licensee or its Affiliate(s) to comply with the terms of this Article VII or this Agreement shall be cause for modification or termination of this Agreement in accordance with the provisions of Article XI below.

ARTICLE VIII

MARKINGS

8.1 Licensee and its Affiliate(s) shall identify and cause to be identified, within a reasonable period of time, Licensed Products with the marking "Licensed Under U.S. Patent (number)" or "U.S. Patent Pending" as permitted or required by statute or identify Licensed Products as patented in any promotional literature used.

8.2 The name of the Government employee inventor(s), the name of the agency or department of the Government or any adaptation of the above shall not be used in any promotional activity without prior written approval from Licensor.

ARTICLE IX

PATENT ENFORCEMENT AND PROSECUTION

9.1 Licensor agrees to take responsibility for the preparation, filing, prosecution and maintenance of any and all patents and patent applications included in the Licensed Patent Technology, subject to Article IV. In its sole and absolute discretion, Licensor may allow Licensee to assume certain or all responsibility for the preparation, filing, prosecution and maintenance of any and all patents and patent applications included in the Licensed Patent Technology on terms and conditions set forth under separate agreement.

9.2 Licensors and Licensees shall notify each other promptly in writing of any infringement or possible infringement of the Licensed Patent Technology, as well as any facts which affect the validity, scope or enforceability of the Licensed Patent Technology that becomes known to either of them. Licensee shall continuously notify Licensors promptly of any action taken or to be taken in accordance with this Article IX to prevent or eliminate such infringement.

9.3 In the event that a declaratory judgment action alleging invalidity of the Licensed Patent Technology shall be brought against the Licensors and/or the Government by a third party, Licensors shall notify Licensee. Licensors do not represent that it or the Government will commence legal action to defend against a declaratory action alleging invalidity. Licensee shall take no action to compel the Licensors or the Government either to initiate or to join in any such declaratory judgment action. If the Licensors and/or Government is or are made a party to any suit by motion or any other action or omission of Licensee, Licensee shall promptly reimburse the Licensors and/or Government on demand for any and all costs, expenses or fees incurred by the Licensors and/or Government as a result of such motion or other action or omission, including, without limitation, any and all Court costs and attorney fees. In connection with or as a result of any action taken or to be taken by Licensee or its Affiliate(s) to prevent or eliminate any infringement, any and all fees, costs and expenses incurred, including, without limitation, attorney's fees, court costs and disbursements, shall be borne entirely by Licensee unless otherwise agreed. A failure by Licensee to strictly comply with the provisions stated herein or to pay in full its reimbursement obligations to the Licensors and/or Government on demand shall constitute a breach of this Agreement.

ARTICLE X

RESERVATION OF RIGHTS

10.1 The license granted in Article III of this Agreement shall be subject to the irrevocable, nonexclusive, nontransferable, royalty-free right of the Government to practice the inventions, described and claimed in the Licensed Patent Technology or any Improvements thereof, on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States, for research and other Government purposes, either alone or with one or more third parties, provided that any third party shall have involvement only to assist the Government for the limited purpose set forth above. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of United States Code, Title 5, Part I, Chapter 5, Subchapter II, Section 552(b)(as amended).

10.2 Licensors, pursuant to the United States Code, Title 35, Part II, Chapter 18, Section 203(as amended), and the underlying federal regulations, reserves the right to require the Licensee and its Affiliate(s) to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, either voluntarily or involuntarily as permitted under applicable law, when necessary to fulfill public health or safety needs. A determination pursuant to this section shall not be subject to the Contract Disputes Act (41 U.S.C. Sec. 601 et seq.)(as amended).

ARTICLE XI

TERM AND TERMINATION

11.1 The term of this Agreement shall commence on the Signature Date, and continue in effect until the expiration of the last to expire patent application or Valid Claim of the Licensed Patent Technology, including any extensions granted under the Patent Term Restoration Act or any other statute (as amended), unless sooner terminated in accordance with this Article XI.

11.2 The Licensors shall have the right to modify or terminate this Agreement and/or the underlying license, in whole or in part, upon the occurrence of any one of the following events (each an "Event of Default"):

(a) Licensee or its Affiliate(s) fails to perform and meet the obligations set forth in Article VII above, and Licensee cannot otherwise demonstrate to Licensors' reasonable satisfaction that Licensee or its Affiliate(s) has taken, or can be expected to take within a reasonable time, effective steps to so perform and meet the obligations set forth in Article VII above;

(b) The Licensors determine that such action is necessary to meet requirements for public use specified by Government regulations issued after the date of this Agreement and such requirements are not reasonably satisfied by the Licensee;

(c) The Licensee makes a misrepresentation or has made a false statement of, or omitted, a material fact in the license application, the Development Plan, or in any Point of Practical Application Report, Additional Information, Report or other information provided to Licensors as required by this Agreement or in the Development Plan;

(d) The Licensee or its Affiliate(s) commits a breach of this Agreement as determined by Licensors;

(e) The Licensee fails to provide or cause to be provided by its Affiliate(s) any Point of Practical Application Report, Additional Information, Report or other information deemed material by Licensors as required by this Agreement;

(f) The Licensee fails to make a payment or to insure payment in full is made as and when required under this Agreement; or

(g) The Licensee is or becomes Bankrupt or has its assets placed in the hands of a receiver or makes any assignment or other accommodation for the benefit or creditors.

11.3 Except for an Event of Default under (d), (f) and (g) above, in making its determination to modify or terminate this Agreement, Licensors shall take into account the normal course of similar commercial development programs conducted under sound and reasonable business practices and judgment and the annual Point of Practical Application Reports, Additional Information, Reports and other information submitted by Licensee under Article V. Prior to

invoking its right to modify or terminate this Agreement and/or the underlying license as a result of an Event of Default, other than under (d), (f) or (g) above or by mutual agreement, Licensor shall furnish Licensee written notice of its intention to modify or terminate, and the Licensee shall be allowed thirty (30) days after the date of such notice to remedy the Event of Default or to show cause why this Agreement should not be so modified or terminated. If Licensee fails to alleviate Licensor's concerns set forth in this Section or fails to take corrective action to Licensor's satisfaction, Licensor may terminate this Agreement.

11.4 The word "**termination**" and cognate words, such as "**term**" and "**terminate**," used in this Article XI and elsewhere in this Agreement are to be read, except where the contrary is specifically indicated, as omitting from their effect the following rights and obligations, all of which survive any termination to the degree necessary to permit their fulfillment or discharge:

(a) Licensee's obligation to supply a terminal Point of Practical Application Report, Additional Information, Report and any other information regarding payments and other matters due to Licensor under this Agreement in the same form as specified in Article V of this Agreement;

(b) Licensor's right to receive or recover and Licensee's obligation to pay License Fees and any other amounts due Licensor hereunder and under the Development Plan accrued or accruable for payment at the time of any termination as specified in Articles IV, V or IX of this Agreement;

(c) Licensee's obligation to maintain records and Licensor's right to conduct a final audit as provided in Article V of this Agreement;

(d) Licenses, releases, and agreements of non-assertion running in favor of customers or transferees of Licensee in respect to Licensed Products sold or transferred by Licensee or its Affiliate(s) prior to any termination and on which payments have been paid as provided in Article IV of this Agreement; and

(e) Any cause of action or claim of Licensor accrued or to accrue, because of any breach or default by Licensee or its Affiliate(s) under this Agreement.

11.5 Licensee shall have the right to terminate this Agreement without cause at any time effective ninety (90) days after written notice as to any patent application or patent within the Licensed Patent Technology. A termination without cause by Licensee may, at the option of Licensor, give rise to an additional termination fee due on demand to cover administrative and related costs and expenses not to exceed [_____] **Thousand Dollars (\$__,000)**, in addition to any and all monies otherwise due and owing hereunder. Licensee shall also have the right to terminate this Agreement in the event Licensor materially breaches the terms and conditions of this Agreement and fails to correct such material breach within ninety (90) days after receipt of written notice from Licensee specifying the breach alleged to have occurred, unless such breach is susceptible to cure and remedied within a reasonable period of time before or after the ninety (90) day period.

11.6 In the event of any termination of this Agreement under this Article XI (other than upon expiration of the term specified in this Article XI), Licensee and its Affiliate(s) shall be permitted, for a period of thirty (30) days or longer with the approval of Licensor, to complete the sale of its existing inventory of Licensed Products and Licensor shall be entitled to the payment of License Fees and any other amounts due Licensor hereunder and as provided in Articles IV, V and IX with respect thereto.

ARTICLE XII

ACKNOWLEDGEMENTS AND REPRESENTATIONS

12.1 Subject to Section 14.3, Licensor acknowledges that: (a) it is the owner of the Licensed Patent Technology; (b) it has the right to grant the rights and licenses granted herein; (c) it will not grant during the term of this Agreement any right, license, or interest in and to the Licensed Patent Technology, or any portion thereof, inconsistent with the license granted to Licensee herein; (d) to its knowledge, no other intellectual property owned by Licensor is necessary to practice the Licensed Patent Technology; and (e) to its knowledge, there are no threatened or pending actions, suits, investigation, claims or proceedings in any way relating to the Licensed Patent Technology.

12.2 Licensee represents and warrants that: (a) it is a corporation duly organized, validly existing and in good standing under the laws of the State of [_____]; (b) the execution, delivery and performance of this Agreement and related materials have been duly authorized by all necessary corporate action on the part of Licensee; (c) it intends and shall use the Licensed Patent Technology solely as contemplated hereunder and shall be primarily liable and responsible for the use of the Licensed Patent Technology by all Affiliates; (d) it shall take any and all necessary and reasonable precautions to comply with the terms and conditions of this Agreement; and (e) it shall operate and conduct its affairs in compliance with all federal, state, and local laws which apply to its performance under this Agreement and, as a result, shall apply for and maintain any necessary licenses required by such laws and immediately notify the Licensor in the event any application is denied, or in any way terminated or limited.

12.3 NO WARRANTIES, EXPRESSED OR IMPLIED ARE OFFERED AS TO THE FITNESS FOR ANY PURPOSE OF THE **MATERIALS OR LICENSED PRODUCTS AND/OR METHODS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT** OR THAT THE **LICENSED PATENT RIGHTS** MAY BE EXPLOITED WITHOUT INFRINGING OTHER PATENT RIGHTS. **LICENSEE** ACCEPTS LICENSE RIGHTS TO THE **LICENSED PATENT RIGHTS, THE LICENSED PRODUCTS AND/OR METHODS, AND THE MATERIALS** “AS IS” AND **USAMRMC** DOES NOT OFFER ANY GUARANTEE OF ANY KIND.

12.4 **Licensee** agrees to indemnify and hold harmless **USAMRMC** and the Government of the United States of America from any claims, costs, damages, or losses that may arise from the practice of the **Licensed patent Rights** or through the use of the **Licensed Products and/or Methods** of the **Materials**.

ARTICLE XIII

DEVELOPMENT PLAN

Concurrent with the execution of this Agreement, the Development Plan prepared and attached by Licensee shall be in effect and relied on by Licensor as an inducement to enter into this Agreement. The Development Plan as may be amended from time to time is attached as **Schedule 2.7 (Development Plan)** hereto.

ARTICLE XIV

GENERAL

14.1 Neither Licensee, nor its successors or assigns, shall, by operation of law or otherwise, transfer or assign this Agreement or encumber the Licensed Patent Technology, without the prior written consent of Licensor in each instance. If any part or all of the shares of stock or equivalent interests of Licensee, or the shares of stock or equivalent interests of any corporation or entity owning shares of Licensee's stock or equivalent interests representing effective voting control of Licensee or its business, shall be transferred by sale, assignment, conveyance, operation of law or other disposition so as to result in a change in the present effective voting control of Licensee or its business, or of such other corporation or entity, by the individual or individuals owning a majority of such shares of stock or equivalent interests, then such transfer shall be deemed to be an assignment or transfer of this Agreement to which Licensor's consent must be given; provided, however, that (a) an assignment incident to a merger or consolidation of Licensee into or with an entity having net assets equal to or greater than the net assets of Licensee as of the date of such transfer, or (b) an assignment or transfer to an entity purchasing the entire business of Licensee, may be made without Licensor's consent (subject to the last sentence below), if such entity shall assume all of the obligations of Licensee under this Agreement pursuant to an instrument reasonably acceptable to Licensor. Notwithstanding any assignment or transfer of this Agreement (whether or not Licensor's consent is required), Licensee shall remain responsible, jointly and severally, with any assignee or transferee for payment of any and all obligations and the performance of all of the covenants, conditions and agreements of Licensee hereunder. In no event shall Licensee, its successors or assigns transfer or assign this Agreement to a party not a citizen, resident or other entity incorporated or arranged under the laws of a state or territory of the United States of America without the express written approval of Licensor.

14.2 This Agreement does not confer any immunity from or defenses under the antitrust laws, the laws and regulations pertaining to or administered by the USFDA, or the export laws nor does it confer immunity from a charge of patent misuse. Furthermore, neither Licensee's, nor its Affiliates' acquisition and exercise of rights hereunder shall be immunized from the operation of any state or Federal law by reason of the source of the grant. This Agreement does not constitute

an endorsement by Licensor of any Licensed Products and neither Licensee, nor its Affiliate(s) shall state or imply in any medium that such endorsement exists as the result of this Agreement.

14.3 Licensor makes no warranty, express or implied, or any representations regarding the patentability, validity or scope of the Licensed Patent Technology or that Licensed Patent Technology may be exploited without infringing patents of third parties.

14.4 Notwithstanding anything to the contrary set forth herein, Licensee and its Affiliate(s) agree that Licensed Products will be manufactured substantially in the United States of America and its jurisdictional territories in compliance with all applicable laws including, without limitation, the United States Code, Title 35, Part II, Chapter 18, Section 209(as amended) and U.S. Presidential Executive Order No. 12591 and that any permitted transfer of technology to foreign entities shall strictly comply with the Export Administration Regulations, 15 CFR Sections 730 – 774(as amended). Licensee and its Affiliates further agree and understand that a failure to strictly comply with such laws and regulations may result in criminal liability under United States laws.

14.5 The decision of Licensor's Representative on any requirement, dispute, interpretation, modification, or termination of this Agreement shall be reduced to writing and a copy mailed or otherwise furnished to Licensee. Such decision shall be final, provided that Licensee may, within thirty (30) days of receiving notice of such decision, submit a written appeal through Licensor's Representative and the Intellectual Property Counsel of the Army to the Judge Advocate General, Department of the Army, Washington, DC 20310-2207, which appeal shall set forth in detail the decision being appealed and the basis of the appeal and may include appropriate supporting materials. Implementation of such decision shall be stayed pending a final resolution of such appeal. Pending such final resolution, Licensee shall proceed diligently with the performance of its obligations under this Agreement.

14.6 Except for complete non-disclosure of certain Intellectual Property Rights specifically designated by Licensor or as otherwise expressly provided herein, the parties agree that, during the term of this Agreement and for ten (10) years thereafter, the receiving party shall keep completely confidential and shall not publish or otherwise disclose and shall not use for any purpose except for the purposes contemplated by this Agreement any Confidential Information furnished to it by the disclosing party hereto pursuant to this Agreement. Licensee may use or disclose information disclosed to it by Licensor to the extent such disclosure is reasonably necessary, in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental laws and regulations or otherwise submitting information to tax or governmental authorities, conducting clinical trials, acquiring potential investors, or making a permitted sublicense or otherwise exercising its rights hereunder, provided that if Licensee is required to make any such disclosure of Licensor's Confidential Information, other than pursuant to a confidentiality agreement acceptable to Licensor, it will give reasonable notice to Licensor of such disclosure and, save to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such information prior to and after its disclosure (whether through protective orders or otherwise). Licensee agrees to keep records of confidentiality agreements between itself and third parties in accordance with the treatment of Confidential Information given in Article V. Licensor may disclose Licensee's

Confidential Information to governmental authorities as may be required by law. The parties understand that from time to time, Licensors may desire to publish or publicly disclose certain summary information regarding this Agreement. In such an event, Licensors shall provide Licensee with a copy of any proposed publication at least thirty (30) days in advance for its review and comment. Following Licensee's review and due consideration of Licensee's comments, Licensors shall be free to publish such information.

14.7 The parties shall notify each other of any changes in name, address, or business status, and any notice or report required to be given under the provisions of this Agreement shall be considered duly given if mailed by first class mail, postage prepaid or by an express/overnight delivery service provided by a commercial carrier, and addressed as follows:

(a) If to Licensors: U.S. Army Medical Research and
Materiel Command
Staff Judge Advocate (MCMR-JA)
504 Scott Street
Fort Detrick, Maryland 21702-5012
Attn: USAMRMC ORTA

(b) If to Licensee: _____

ATTN: _____

Notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier.

14.8 This Agreement shall be governed by and construed in accordance with the federal laws of the United States of America as interpreted and applied by the Federal courts in the District of Columbia, United States of America, without giving effect to principles of conflicts of laws. Each of the parties hereby irrevocably submits to the jurisdiction of any federal court sitting in the District of Columbia over any action or proceeding arising out of or relating to this Agreement and each hereby waives the defense of an inconvenient forum for the maintenance of such action.

14.9 This Agreement, together with all schedules and attachments, constitutes the entire understanding between the parties and neither party shall be obligated by any condition or representation other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.

14.10 All prior reviews and approvals required by regulations or law have been obtained by the Licensors prior to the execution of this Agreement. The Licensors' Director executing this Agreement has the requisite authority to do so.

14.11 Failure of any party to enforce any term, covenant, or condition herein contained shall not be deemed to be a waiver of such term, covenant, or condition herein contained.

14.12 Neither party shall be in default hereunder by reason of its delay in the performance of, or failure to perform, any of its obligations hereunder, other than Licensee's obligations to make payments to Licensor in accordance with the terms of this Agreement, if such delay is caused by war, strikes, acts of God or the public enemy, riots, without the fault or negligence of the other party. During the pendency of such intervening event, each of the parties shall take all reasonable steps to furnish the services required hereunder by other means, and, in any event shall, upon termination of such intervening event, forthwith resume obligations under this Agreement.

14.13 The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.

14.14 **Licensee** agrees in its use of any **Licensor**-supplied materials to comply with all applicable statutes, regulations, and guidelines. **Licensee** agrees not to use the **Materials** or the **Licensed Products and /or Methods** for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46.

(Signature Page to follow)

Rest of Page left intentionally blank

IN WITNESS WHEREOF, each of the parties hereto has caused this Agreement to be executed in triplicate originals by its duly authorized officers or representatives on the day and year set forth below.

FOR LICENSEE: [_____]

BY: _____

NAME: _____

TITLE: [President]

DATED: _____

WITNESS: _____

DATED: _____

FOR LICENSOR: [_____]

BY: _____

NAME: [_____]

Colonel, U.S. Army

TITLE: Commander & Director, [_____]

DATED: _____

WITNESS: _____

DATED: _____

Schedule 2.2 (Affiliates)

Schedule 2.7 (Development Plan)

Schedule 2.16 – A (Existing Patents)

I. **Patents.**

II. **Patent Applications.**

Schedule 2.16 – B (Additional Patents and Patent Applications)

II. **Additional Patents.**

III. **Additional Patent Applications.**

IV. **Ancillary Intellectual Property Rights.**